

# Exhibit C

## Statement of Facts

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA,

v.

PRACTICE FUSION, INC.,  
Defendant.

Docket No. 2:20-cr-11

**STATEMENT OF FACTS**

The following Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the “Agreement”) between the United States Attorney’s Office for the District of Vermont (the “Government”) and PRACTICE FUSION, INC. (“PRACTICE FUSION”). PRACTICE FUSION hereby agrees and stipulates that the following information is true and accurate. PRACTICE FUSION admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below. Should the Government pursue prosecution that is deferred by the Agreement, PRACTICE FUSION agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts establish beyond a reasonable doubt the charges set forth in the Information deferred by the Agreement:

**I. INTRODUCTION**

1. Beginning in or around Fall 2013 Defendant PRACTICE FUSION solicited remuneration from a pharmaceutical company (“Pharma Co. X”) in exchange for creating and embedding an alert, known as a clinical decision support (“CDS”) alert, in PRACTICE FUSION’s electronic health record (“EHR”) to prompt doctors to take certain clinical actions for purposes of increasing Pharma Co. X’s extended release opioid (“ERO”) prescriptions. This CDS alert (“the Pain CDS”) suggested doctors focus on assessing and treating a patient’s pain

symptoms, and provided the healthcare provider a list of potential care plan treatment options. The Pain CDS suggested treatments, including the prescription of opioid medications, without discussing the medical appropriateness of each option.

2. The remuneration offered and paid by Pharma Co. X and solicited and received by PRACTICE FUSION in return for PRACTICE FUSION designing the Pain CDS with a purpose of increasing Pharma Co. X's ERO sales, portions of which were paid for by federal health care programs, was a kickback in violation of 42 U.S.C. § 1320a-7b(b)(1)(B) & (2)(B).

3. PRACTICE FUSION and Pharma Co. X's agreement and acts in furtherance of their unlawful kickback scheme was a conspiracy to violate the Anti-Kickback Statute, in violation of 18 U.S.C. § 371.

## **II. BACKGROUND**

At times relevant to this Information:

4. "Pharma Co. X" (a pseudonym) was a United States-based pharmaceutical company whose products included branded extended release opioids.

5. Defendant PRACTICE FUSION was a Delaware corporation with headquarters in San Francisco, California. PRACTICE FUSION was a cloud-based EHR company that generally provided its cloud-based EHR product to healthcare providers without charge.

6. Employee # 1 was a PRACTICE FUSION Life Sciences Sales Representative initially in charge of the Pharma Co. X account.

7. Employee #2 was PRACTICE FUSION's Senior Vice President for Life Sciences Practice and Strategic Partnerships.

8. Employee #3 was PRACTICE FUSION's Chief Commercial Officer ("CCO").

9. Employee #4 was PRACTICE FUSION's Chief Medical Officer.

10. Employee #5 was PRACTICE FUSION's Director of National Accounts and was ultimately responsible for the Pharma Co. X account at the time the Pain CDS deal closed.

Employee #5 was the Practice Fusion employee credited with closing the Pain CDS deal and the only employee provided a commission in connection with the deal.

11. Employee #6 was PRACTICE FUSION's Director of Strategic Development, Life Science Partnerships.

12. Pharma Co. X Employee #1 was Pharma Co. X's Director of eMarketing.

13. Pharma Co. X Employee #2 was a Pharma Co. X Brand Manager in charge of one of Pharma Co. X's ERO brands.

14. PRACTICE FUSION provided EHR services to tens of thousands of active healthcare provider users in the United States, including in Vermont, and its software was used during millions of patient encounters each month.

15. Though PRACTICE FUSION offered its EHR to healthcare providers free of charge, PRACTICE FUSION had various sources of revenue. Federal regulations provided for the implementation of CDS alerts in EHR software. Practice Fusion derived revenue from this clinical functionality in the form of payments from pharmaceutical companies in exchange for creating CDS alerts in its EHR, which was used in doctors' offices across the country.

16. PRACTICE FUSION's CDS alerts typically worked as follows for a healthcare provider using the PRACTICE FUSION EHR: a message would appear on the PRACTICE FUSION EHR alerting the healthcare provider that the provider should consider certain clinical information, perform certain tests or assessments, and complete certain documentation, given the particular personal health information and circumstances of the patient before the provider at that moment.

17. PRACTICE FUSION understood that Pharma Co. X provided remuneration in exchange for the Pain CDS because the CDS could boost sales of Pharma Co. X's ERO products.

18. PRACTICE FUSION understood that it was unlawful to sell CDS programs based on anticipated returns on investment that a pharmaceutical company client could achieve through the CDS, and that any CDS program must be consistent with any applicable evidence-based medical guidelines and Department of Health and Human Services ("HHS") Centers for Medicare and Medicaid Services ("CMS") Clinical Quality Measures ("CQM").

19. Extended release opioids are highly addictive narcotics that are properly prescribed only in limited circumstances. According to the United States Food and Drug Administration ("FDA") approved labeling for Pharma Co. X's leading ERO that product was, as of 2015, indicated "for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." The FDA-approved labeling for Pharma Co. X's leading ERO product directed: "Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release formulations, reserve [Pharma Co. X's ERO product] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain."

20. The FDA-approved labeling says Pharma Co. X's primary ERO is "[t]o be prescribed only by healthcare providers knowledgeable in use of potent opioids for management of chronic pain."

21. The Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b) prohibited PRACTICE FUSION from knowingly and willfully soliciting or receiving remuneration in return for

“arranging for or recommending” ordering any good or item for which payment may be made in whole or in part under a Federal health care program. PRACTICE FUSION knowingly and willfully violated the Anti-Kickback statute through its solicitation and receipt of remuneration from Pharma Co. X in connection with the Pain CDS.

22. 18 U.S.C. § 371 prohibits conspiracies and provides that “[i]f two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.” PRACTICE FUSION conspired with Pharma Co. X to violate the Anti-Kickback Statute through its solicitation and receipt of remuneration from Pharma Co. X in connection with the Pain CDS.

### **III. OVERVIEW OF PRACTICE FUSION’S SOLICITATION OF REMUNERATION FROM PHARMA CO. X**

23. PRACTICE FUSION began discussing the prospect of using its EHR in furtherance of Pharma Co. X’s marketing goals with Pharma Co. X personnel as early as fall 2013. These discussions included the possibility of using the PRACTICE FUSION EHR to screen potential patients for whether they were suitable for long-term opioid therapy, including assessing whether the patient had a history of substance abuse.

24. PRACTICE FUSION and Pharma Co. X did not pursue a CDS alert to assist doctors in screening patients for risk of opioid abuse; instead, the parties developed a CDS to increase sales of Pharma Co. X’s ERO products.

25. As discussions between the parties increasingly focused on Pharma Co. X’s commercial objectives, Employee #1 was counseled in an internal PRACTICE FUSION email in April 2014 that “[i]ndicating that [Pharma Co. X] influenced clinical decisions through sponsored



money has legal implications versus a marketing program where a banner can be displayed and influence prescribing behavior.”

26. In or around May 2014, PRACTICE FUSION continued its solicitation of Pharma Co. X by forwarding to Pharma Co. X news stories concerning PRACTICE FUSION’s implementation of a CDS program paid for by a vaccine manufacturer.

27. Between May 2014 and March 2015, representatives from PRACTICE FUSION and Pharma Co. X continued to communicate regularly regarding potential transactions between the two companies.

28. In a March 23, 2015 internal PRACTICE FUSION email—written in preparation for a scheduled March 31, 2015 meeting at Pharma Co. X—Employee #1 described the opportunity to sell a CDS program to Pharma Co. X by explaining to PRACTICE FUSION colleagues that Pharma Co. X “has communicated that the average dosage of [Pharma Co. X’s leading ERO] is declining” and that “[p]roviders are hesitant about using high dosages to combat pain for a variety of reasons, mostly political pressure.” The email further stated that “[a]s a result, [Pharma Co. X] is toying with the idea of using Pain Assessment tools with the provider at every visit and before every RX.” RX is an abbreviation for prescription.

29. PRACTICE FUSION understood Pharma Co. X was concerned that as a result of heightened public awareness of the dangers of opioid use, healthcare providers were prescribing lower dosages of opioids. PRACTICE FUSION thus marketed its medical software as having the potential to “influence provider behavior” and counteract Pharma Co. X’s economic concerns regarding providers prescribing fewer and lower dosages of opioids.

**A. PRACTICE FUSION’S MARCH 31, 2015 SOLICITATION TO PHARMA CO. X AND ENSUING FOLLOW-UP SOLICITATIONS**

30. On or about March 31, 2015, PRACTICE FUSION representatives travelled to Pharma Co. X's headquarters to continue soliciting payment from Pharma Co. X in exchange for a CDS. PRACTICE FUSION solicitation materials included a PowerPoint presentation, commonly referred to as a "pitch deck." PRACTICE FUSION's pitch deck indicated that a pain CDS would be "based on" the "brand objectives" of Pharma Co. X's three extended release opioid products. These objectives included targeting "opioid naïve patients"—i.e., patients who were not previously prescribed opioids—and targeting patients who were using immediate release opioids ("IROs"), which were less dangerous than EROs, but also less profitable to Pharma Co. X.

31. Pharma Co. X advised PRACTICE FUSION that it wished to utilize a CDS to "target" the opioid naïve and IRO users. Those patients represented potential additional users of Pharma Co. X's EROs. Further, Pharma Co. X would make more money selling its drugs if PRACTICE FUSION's CDS helped "keep[] an appropriate patient on a consistent dose . . . ." PRACTICE FUSION thus recommended creating tools within its EHR that would "identify care gaps for appropriate patients," "provide validated tools for providers to better manage patients," and to "plan for and measure" patient outcomes.

32. Following the March 31, 2015 presentation, Employee #2 emailed Employee #3 stating that "next steps" with respect to the Pharma Co. X solicitation included "build[ing] model to show potential commercial impact of increased patients being screened for pain and risk of opioid abuse."

33. According to this March 31, 2015 email, the PRACTICE FUSION personnel who were to "model" the "commercial impact" to Pharma Co. X's drug sales from the CDS included: Employee #1, Employee #4, Employee #5, and Employee #6.



34. Employee #5 modelled the “commercial impact” that would accrue to Pharma Co. X as a result of the Pain CDS causing an increase in ERO prescriptions. PRACTICE FUSION calculated that Pharma Co. X would obtain a return on investment (“ROI”) of between 5.8 and 7.8 times its cost if it implemented the PRACTICE FUSION Pain CDS.

35. The model, as revised in an internal April 24, 2015 PRACTICE FUSION email from Employee #5, estimated that Pharma Co. X would achieve a “patient gain” of two thousand seven hundred seventy-seven (2,777) and between \$8,458,232 and \$11,277,643 in additional opioid revenue by implementing the CDS.

36. PRACTICE FUSION developed a model to show the “commercial impact” to Pharma Co. X of a pain CDS, and Pharma Co. X eventually entered into a contract with PRACTICE FUSION for the Pain CDS based on the parties’ mutual expectation of increased ERO sales.

37. An April 1, 2015, email containing a prior version of the April 24 model stated that PRACTICE FUSION “could use” the following “values to present an economic benefit of the proposed program” to Pharma Co:

- a. “Value of *keeping an appropriate patient on a consistent dose* of one of the products throughout the 2 year term of the program”;
- b. “Value of *conversion from IR to ER and consistent dosing* over the term of the program”; and
- c. “Value of a % market share in the branded ERO space; [Pharma Co. X] mentioned they enjoy an 83% share in the branded ERO space. We can track and measure two things during the program. Share of the current branded EROs on

our platform and *potential new market entrants to ERO therapy as a result of the clinical intervention.*” (emphasis added).

38. PRACTICE FUSION thus sought remuneration from Pharma Co. X to design the Pain CDS to cause healthcare providers to extend the duration of ERO prescriptions, convert patients receiving IROs to EROs, and to increase the overall market of ERO-using patients and to measure its ability to deliver such results.

39. In an April 22, 2015 internal PRACTICE FUSION email discussing follow up communications to Pharma Co. X, Employee # 5 advised: “Since this is being sent to a marketing audience the idea of ROI has to be part of the plan to justify the costs of the program.”

40. PRACTICE FUSION did not include its calculations of increased opioid patient volume, increased opioid sales, or increased persistency to opioid products in the pitch materials provided to Pharma Co. X. Rather, on or about April 23, 2015, Employee #5 directed in an internal PRACTICE FUSION email pertaining to the Pharma Co. X CDS written proposal: “Don’t include the ROI in the proposal. We’ll walk the client through the ROI.”

41. On April 28, 2015, Employee #2 described the final Pharma Co. X pitch deck as “concise and will allow us to voice over what we need to regarding how the program works and its commercial impact.”

42. On April 29, 2015, Employee # 2 stated in an internal email referring to the follow up with Pharma Co. X that “[t]he goal here is to sell it as a study-but get commercial \$ moved over or added to the funding to make the deal work.” This same email observed that there was “urgency” for PRACTICE FUSION to generate revenue.

43. On May 11, 2015, Employee #6 asked Employee #5 if he had “the final pricing model you used for [Pharma Co. X]?” Employee #6 then wrote: “Actually...without saying

ROI...I mean the ROI spreadsheet ;).” Employee #5 then provided the Pharma Co. X ROI analysis.

**B. PRACTICE FUSION’S SEPTEMBER 1, 2015 PRESENTATION AT PHARMA CO. X HEADQUARTERS AND SUBSEQUENT FOLLOW-UP**

44. Employee #5 emailed personnel in Pharma Co. X’s marketing department on July 16, 2015, “to re-engage around the Practice Fusion Clinical Decision Support Real World Evidence Pain Management program.” He stated “[w]e feel that the proposed program can help meet the strategic commercial needs of the pain franchise at [Pharma Co. X.]”

45. Prompted by the July 16, 2015 email described in the preceding paragraph, PRACTICE FUSION and Pharma Co. X’s marketing personnel scheduled an additional presentation at Pharma Co. X’s headquarters for PRACTICE FUSION to propose the Pain CDS program in greater detail. This meeting was scheduled for September 1, 2015, at Pharma Co. X’s headquarters.

46. On or about August 17, 2015, Employee #5 discussed PRACTICE FUSION’s proposal with two Pharma Co. X employees, Pharma Co. X Employee # 1 and Pharma Co. X Employee #2. In an email describing that discussion, Employee #5 stated that PRACTICE FUSION’s “proposed solution” would include, among other features, “appropriate pain assessment tools/screeners that will help providers in the decision to initiate ERO products,” and “[u]nbranded clinical messaging to reinforce appropriate use of EROs in patient populations – IRO users, chronic NSAID users, tramadol, etc.” This email further explained that Pharma Co. X Employee #1 desired to see a “draft strategy by weeks end to discuss and refine for presentation to the broader commercial team during [the] meeting in Sept.”

47. On or about August 21, 2015, Employee #5 forwarded a preliminary version of the September 1, 2015 presentation to Pharma Co. X Employee #1.

48. On or about September 1, 2015, two PRACTICE FUSION employees, including Employee #5, travelled to Pharma Co. X's headquarters to propose that Pharma Co. X pay PRACTICE FUSION approximately \$1,000,000 to develop and implement the Pain CDS to influence health care providers to prescribe more EROs.

49. Pharma Co. X marketing personnel representing each of its three ERO brands attended the September 1, 2015 presentation. The presentation included a pitch deck in which PRACTICE FUSION proposed the CDS program focus on the treatment of pain by:

- a. "Leverag[ing] Practice Fusion Platform to deliver Clinical Decision Support and measure the impact and real world outcomes on patient care."
- b. Delivering "clinical patient-centric provider messages" targeted at healthcare providers with "opioid naïve patients with chronic pain," and with patients currently receiving immediate release oxycodone and hydrocodone; and
- c. "Leverag[ing] the Practice Fusion EHR platform to help providers assess, diagnose, and treat Chronic Pain."

50. The proposal also included PRACTICE FUSION providing "educational messages" targeted to healthcare providers with patients with diagnoses of "chronic pain and with history of non-Opioids in their chart."

51. Employee #5 led discussion of the Pain CDS.

52. After the September 1, 2015 meeting, a PRACTICE FUSION employee provided the pitch materials by email on September 2, 2015 to the PRACTICE FUSION employee who advised Employee #1 regarding the legal implications of using a CDS as a marketing tool, as described in paragraph 25, above. That employee in turn forwarded those materials to another PRACTICE FUSION employee by email with a message that included: "I understand that the

[Pharma Co. X] proposal has shifted to a commercial focus and that marketing folks were in the room instead of outcomes[.]” The message also included “[t]here are several things incorrect with this presentation /proposal from pricing to products. Please do not share. Just be aware....”

53. PRACTICE FUSION included a study as part of the September 1 proposal. A September 2 internal PRACTICE FUSION email observed, however, that Pharma Co. X was not interested in a study: “we were talking to product managers, and they could care less about RWE [real world evidence studies]. For them, this was all about marketing.” The email further stated that during the September 1 meeting with Pharma Co. X “I made it clear that we would measure success (metrics, switches from IR to ER, etc.)[.]” The study was included in the proposal, in part, to make the deal appear as a legitimate medical project, and not a commercial endeavor.

54. A September 1, 2015 internal PRACTICE FUSION email from Employee #5 confirmed that Pharma Co. X’s “brands” would contribute equally to the cost of the program “since this is a non branded effort.”

55. On September 4, 2015, Employee #5 emailed Pharma Co. X Employee # 1 with a “revised deck” that was “based on our meeting this week.” This “revised deck” included a new slide devoted to “Project Goals.” Those goals included (among others): “Educate providers around appropriate patients for [extended release opioid] therapy”; “Identify care gaps through clinical support alert tools at the point of care”; “Aid providers in identifying patients who are experiencing pain and prompt corrective action or change in therapy”; and to provide Pharma Co. X a “[d]etailed analysis of effectiveness of clinical decision support alerts on treatment patterns (focus on IR/non opioid to ERO conversion) and outcomes (quarterly metrics).”

#### **IV. PHARMA CO. X AGREED TO PROVIDE PRACTICE FUSION REMUNERATION IN EXCHANGE FOR THE CREATION OF A PAIN CDS**



**THAT WOULD INFLUENCE PHYSICIANS AND INDUCE PRESCRIBING OF EXTENDED RELEASE OPIOIDS**

56. Shortly after the September 1, 2015 meeting, Pharma Co. X and PRACTICE FUSION moved forward with designing the Pain CDS as pitched by PRACTICE FUSION.

57. Pharma Co. X Employee #1 and PRACTICE FUSION personnel—including Employee #4 and other Practice Fusion clinical personnel—began designing the Pain CDS alert. Employee #5 and Pharma Co. X Employee #1 reviewed the draft Pain CDS from PRACTICE FUSION’S clinical personnel and proposed edits that would enhance the likelihood that the Pain CDS would increase prescriptions.

58. For example, a January 29, 2016 email from Pharma Co. X Employee #1 to Employee #5 included a proposed edit to the Pain CDS workflow that allowed healthcare providers to “check off ‘Extended Release Opioid initiated’ – by adding this we think this will trigger the prescriber to assess again if a change in therapy is needed as a follow up.”

59. Similarly, on February 3, 2016, Employee #5—who also was not a physician and similarly lacked familiarity with treating pain and prescribing schedule II narcotics—responded by email with a draft of the proposed CDS alert that contained “Extended Release Opioids” as a treatment option as had been requested by Pharma Co. X’s drug marketers. Employee #4 approved the change to the Pain CDS workflow. Employee #4 also lacked experience with treating pain and prescribing EROs. As implemented, “Extended Release Opioids” were referenced parenthetically in the care plan portion of the Pain CDS, as one of three types of opioid treatment.

**A. THE PAIN CDS CONTRACT**

60. PRACTICE FUSION and Pharma Co. X entered into a written statement of work (“SOW”) contracting for the Pain CDS effective March 1, 2016, in which they agreed to, among

other things: provide health care providers “who utilize the Practice Fusion Solution” with a CDS Program “directed at chronic pain management treatment with immediate release opioids and chronically used NSAIDs” that would “support the identification of and/or treatment of patients who are recommended to be screened for or receive the treatments specified in” what the contract described as “gold standard evidence-based clinical guidelines” that were attached to the contract. The SOW attached Clinical Quality Measure #131, which called for health care providers to prepare “documentation of a follow-up plan when pain is present” for patients over 18 years old “with documentation of a pain assessment using a standardized tool(s).”

61. The contract specified that Pharma Co. X “shall be the funding source for the CDS Program.”

62. In the contract, Pharma Co. X and PRACTICE FUSION agreed that Pharma Co. X would pay PRACTICE FUSION \$144,600 for a “Retrospective Analysis” and \$815,100 for CDS-related work.

63. Despite the parties’ mutual understanding that the purpose of the program was to increase ERO prescriptions, the contract stated that the “Parties agree and acknowledge that the collaboration project will follow national evidenced-based guidelines, and will not encourage the prescribing or utilization of a [Pharma Co. X]-specific product or services.”

64. The contract also called for PRACTICE FUSION to target “awareness messages” about the Pain CDS at healthcare providers who prescribed NSAIDs and IROs.

65. Pursuant to the parties’ SOW, PRACTICE FUSION and Pharma Co. X were to “participate in an initial RWE Study kick-off meeting” and “[d]uring the course of the RWE Study, regular meetings will be held between [Pharma Co. X] and Practice Fusion teams to review progress on the RWE Study and the Project work plan. These meetings, which will be

scheduled at RWE Study kick-off will enable continued attention to RWE Study tasks and deliverables.”

**V. PHARMA CO. X AND PRACTICE FUSION DESIGN THE PAIN CDS**

66. A recap of the initial conference call between PRACTICE FUSION and Pharma Co. X to design the project confirmed that the “success” of the Pain CDS program would be “increased prescriptions for [Pharma Co. X’s] meds APPROPRIATELY (EROs in general and specifically [Pharma Co. X’s]).” (emphasis in original). Other records noted that while there would be no specific pharmacotherapy intervention as part of the CDS program, the prescribing of extended release opioids “will likely be one of the follow-up plans when pain scale is high.”

67. Contemporaneous to the development of the commercially-focused Pain CDS the United States Center for Disease Control and Prevention (“CDC”) published the “CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016” (hereafter “CDC Guidelines”). The CDC Guidelines were published on or about March 15, 2016 and were circulated within both Pharma Co. X and PRACTICE FUSION shortly after their release, including among those involved in developing the Pain CDS.

68. Both PRACTICE FUSION and Pharma Co. X employees involved in creating the Pain CDS—including Employee #4—possessed and reviewed the CDC Guidelines during development of the Pain CDS; yet, the parties did not incorporate the recommendations contained in those guidelines.

69. The CDC Guidelines stated, among other things:

- a. extended release opioids “should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week”;

- b. “When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids”;
- c. “When opioids are started, clinicians should prescribe the lowest effective dosage”;
- d. “Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient”;
- e. “The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent”; and
- f. The Guidelines encouraged providers to “[b]e explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely.”

70. In or about April 2016, Pharma Co. X personnel requested the Pain CDS include a list of possible treatments for pain consisting of the treatments identified within a 2016 New England Journal of Medicine (“NEJM”) article entitled “Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies,” plus opioids. That article admonished, among other things, that it was not intended to provide clinical instruction in the treatment of chronic pain,

and that the benefits of opioids for treatment of chronic pain were “much more questionable” than for treatment of acute pain.

71. Similar to the CDC Guideline, the NEJM article identified “concerns about overdosing and abuse by patients” and “Factors associated with the risk of opioid overdose or addiction,” which included, amongst other things:

- a. Daily dosages greater than 100 MME [morphine milligram equivalents];
- b. Long-acting or extended-release formulation;
- c. Combination of opioids with benzodiazepines;
- d. Long-term opioid use (greater than 3 months);
- e. Depression;
- f. Substance-use disorder; and
- g. History of overdose.

72. The NEJM article further provided a table of “Mitigation Strategies against Opioid Diversion and Misuse.” These strategies included, among other things:

- a. Screening tools to identify patients with a substance-use disorder, such as the Opioid Risk Tool; the Screener and Opioid Assessment for Patients with Pain (SOAPP); the Brief Risk Interview;
- b. Use of data from the Prescription Drug Monitoring Program;
- c. Use of Urine Drug Screening; and
- d. Doctor-patient agreement on adherence.

73. Despite reviewing and purportedly relying on the NEJM article in developing the Pain CDS, Pharma Co. X and PRACTICE FUSION did not design the Pain CDS to address any



of the factors listed above as risks of opioid overdose and addiction; nor did the parties incorporate any of the “Mitigation Strategies against Opioid Diversion and Misuse.”

74. On May 11, 2016, a PRACTICE FUSION employee reported on a call with Pharma Co. X personnel about the development of the CDS and observed that he kept “hearing the client [Pharma Co. X] revert back to ‘Rx lift’ as the primary objective of the program, this came up in the kickoff meeting and again during last week’s meeting when we were talking about the objectives of the prospective and retrospective analyses.” “Rx lift” refers to increased prescriptions.

## **VI. THE PAIN CDS IN OPERATION IN DOCTORS’ OFFICES ACROSS THE COUNTRY**

75. The CDS program went live on PRACTICE FUSION’s platform on or about July 6, 2016. As finalized, the Pain CDS contained three separate alerts. The first alert encouraged health care providers to record a pain score. The second alert suggested that doctors take a Brief Pain Inventory (“BPI”) of patients who had recorded two or more pain scores of four or more (on a zero to ten point scale) within the previous three months, or that had a chronic pain diagnosis. The BPI further focused providers on the patient’s pain symptoms and included a list of questions on the severity and impact of the patient’s pain, and prompted the patient to describe the patient’s pain “now,” “on the average,” and at its “worst” and “least” during the previous 24 hours. The third alert indicated that a follow up plan should be created for treating the patient’s pain, appearing only if the patient reported pain on the pain scale of four or higher twice within four months, or if a patient with chronic pain has had a BPI completed.

76. The CDS utilized a drop-down menu of options for pain treatments to populate the treatment plan. This menu listed the following options, on equal footing with each other:

FOLLOW-UP PLAN	
	Q
Adjuvant pharmacotherapy (e.g. topical agents, antispasmodics)	
Biofeedback	
Education (e.g. reassurance; exercise; appropriate activities)	
Interventional or neural stimulation therapy	
Nonopioid analgesics (e.g. acetaminophen; NSAIDs; antidepressants)	
Nonpharmacologic (e.g. physical therapy; cognitive-behavioral therapy)	
Opioid Therapy (short-acting, long-acting/extended release)	
Pain resolved	
Referral to pain specialist	
Surgical Procedure	

77. As implemented, the Pain CDS alert deviated from the guidelines in several respects, including:

- a. the Pain CDS's list of treatment options was in part sourced from the NEJM medical journal article that was not intended to address how to treat patients with chronic pain;
- b. in addition to the non-opioid analgesics and other alternative pain-treatment options identified by the NEJM article, PRACTICE FUSION and Pharma Co. X added "Opioid Therapy (short-acting, long-acting/extended release)" as a treatment option within the care plan without regard for whether the patient's condition was indicated for immediate or extended release opioids in that:
  - i. EROs are listed as an option for patients with less than severe pain;

ii. EROs are listed as an option for patients with pain without regard to whether the pain could be adequately treated by non-ERO options;

iii. EROs were suggested as a treatment option for patients whose pain was not chronic, but who presented with separate complaints of acute pain within three months.

c. The Pain CDS instructed providers to record a treatment plan only when pain was classified as “chronic” or was above a certain threshold over a period of time. The CQM’s performance standards required providers to record a treatment plan any time the pain assessment was documented as positive.

d. The Pain CDS did not incorporate recommendations from the CDC Guidelines and did not incorporate the substance of the NEJM article from which the CDS sourced a list of treatment options.

e. The Pain CDS listed EROs as a treatment option on equal footing with IROs and non-opioid therapy—contrary to accepted medical practice.

f. The Pain CDS listed EROs as an option for patients who had not previously received opioid therapy (i.e., the opioid naïve).

78. The Pain CDS also deviated from Pharma Co. X’s extended release opioids’ labelled indications in that it listed EROs as a treatment option without regard to whether the patient’s pain was severe or whether “alternative treatment options were ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain” or the provider had the adequate expertise to prescribe EROs.

79. In sum, the value to Pharma Co. X of increased referrals arranged by the Pain CDS was used to justify the remuneration provided; the CDS was not consistent with guidelines

such as the CDC Guideline; the CDS was inconsistent with the applicable CQM; and the CDS was funded by Pharma Co. X's marketing department and Pharma Co. X's drug marketers were involved in its design.

**A. AFTER IMPLEMENTATION PRACTICE FUSION AND PHARMA CO. X CONTINUED TO VIEW OF THE PAIN CDS AS A COMMERCIAL PROGRAM**

80. PRACTICE FUSION and Pharma Co. X planned an in-person meeting at Pharma Co. X's headquarters to report on a retrospective study and the results of the Pain CDS. PRACTICE FUSION was instructed to answer whether "the CDS alerts change prescribing behavior" and "show ERO prescribing as it tracks with CDS." Pharma Co. X continued to have an interest in understanding whether and by what measure the Pain CDS was achieving its intended goal of influencing ERO prescribing in ways commercially favorable to Pharma Co. X's drug sales.

81. On or about December 14, 2016, PRACTICE FUSION personnel conducted the presentation at Pharma Co. X's headquarters. During this meeting, PRACTICE FUSION reported that through November 30, 2016, the Pain CDS had alerted during 21 million patient visits, involving 7.5 million patients, and 97,000 healthcare providers. During this presentation PRACTICE FUSION explained:

- a. that since Pain CDS alerts went into effect "there is a general shift toward EROs from IROs";
- b. the "biggest shift [was] within Emergency Medicine, Orthopedics, and Pain Medicine"; and
- c. "[w]e also see a general shift from IROs to EROs-which is more pronounced in certain specialties and therapeutic areas."

82. PRACTICE FUSION's presentation included charts and graphs that depicted the relative share of IROs vs. EROs as prescribed by doctors utilizing the PRACTICE FUSION EHR since the Pain CDS went into effect.

83. PRACTICE FUSION also analyzed the effectiveness of various pain treatment options, including adjuvants, COX-2s, EROs, IROs, and NSAIDs, finding that overall EROs were the least effective in lowering pain as only 39.17% of such patients had lower pain, as the below chart from the December 14, 2016 presentation shows.

### Pain Score Summary

Adjuvant	Change (#)	Change (%)	COX-2	Change (#)	Change (%)	ERO	Change (#)	Change (%)
Lower Pain	3,022	41.96%	Lower Pain	394	47.30%	Lower Pain	805	39.17%
No Change	1,707	23.70%	No Change	195	23.41%	No Change	611	29.73%
Higher Pain	2,473	34.34%	Higher Pain	244	29.29%	Higher Pain	639	31.09%

  

IRO	Change (#)	Change (%)	NSAID	Change (#)	Change (%)
Lower Pain	3,622	46.31%	Lower Pain	5,647	45.45%
No Change	1,818	23.24%	No Change	2,724	21.93%
Higher Pain	2,382	30.45%	Higher Pain	4,053	32.62%

84. Similarly, PRACTICE FUSION's data found that EROs were the second least effective treatment option in lowering pain amongst patients with chronic pain.

### Pain Score Summary (Chronic Pain)

Adjuvant	Change (#)	Change (%)	COX-2	Change (#)	Change (%)	ERO	Change (#)	Change (%)
Lower Pain	547	40.22%	Lower Pain	53	47.75%	Lower Pain	259	40.41%
No Change	329	24.19%	No Change	30	27.03%	No Change	185	28.86%
Higher Pain	484	35.59%	Higher Pain	28	25.23%	Higher Pain	197	30.73%

  

IRO	Change (#)	Change (%)	NSAID	Change (#)	Change (%)
Lower Pain	626	42.33%	Lower Pain	576	40.88%
No Change	399	26.98%	No Change	375	26.61%
Higher Pain	454	30.70%	Higher Pain	458	32.51%



85. PRACTICE FUSION additionally provided data and information to Pharma Co. X identifying the “Top Diagnosis Groups” that received EROs.

86. A Pharma Co. X attorney was present at the December 14, 2016 meeting. She expressed reservations about the Pain CDS, noting that it had not received appropriate legal review within Pharma Co. X, and considered “pausing” the program.

87. Rather than pausing the program, the Pain CDS program continued. In a series of emails from December 2016 and January 2017, Pharma Co. X requested PRACTICE FUSION to supply materials related to the Pain CDS for the purposes of Pharma Co. X’s legal review.

88. Employee #5 gathered the materials to be provided to Pharma Co. X for this belated legal review. The materials provided for this purpose did not explain the commercial objective of the program.

**B. THE PAIN CDS RESULTED IN ADDITIONAL PRESCRIPTIONS OF PHARMA CO. X’S EROs**

89. The Pharma Co. X-developed CDS alert was live on the PRACTICE FUSION platform from on or about July 6, 2016 to the Spring of 2019. The Pain CDS alerted more than approximately 230,000,000 times during this period.

90. Health care providers who received the Pain CDS alerts prescribed EROs at a higher rate than those that did not.